Design Development Plan Rev C

Rebotix	Author Joe Morrison	Document Number / Rev DPPR1001; Rev C	Page 1 of 11
Title: Design Development Plan "Endowrist"			

Objective:

Establish method for remanufacturing robotic surgical EndoWrists ("Wrists") originally manufactured by Intuitive Surgical and utilized as an accessory in Intuitive's Da Vinci robotic surgical systems ("Host System"). The objective is to offer users a serviced Wrist and an alternative to purchasing a new OEM Wrist replacement.

Refer to Attachment A for a list of wrists to be remanufactured.

Goals:

1. To remanufacture previously used Wrists so that functionality and safety are equivalent to OEM Wrists
2. Remanufactured Wrist to be 100% compatible with Host System.
3. Extend the useful life of the remanufactured Wrist to the original OEM value plus 1. Ex. If the original wrist was rated for 10 uses, the remanufactured wrist would be rated for 10 + 1 or 11 reuses.

Device Description:

The subject device(s) consist of a family of endoscopic instruments with either grasping or cutting end effectors to be used with the Intuitive Surgical da Vinci Endoscopic Instrument Control System. These instruments attach to the two instrument manipulator arms on the Intuitive Surgical Endoscopic Instrument Control System. The instruments are re-usable (for a limited number of uses), are provided non-sterile, and must be cleared and sterilized before used (pre-vacuum autoclave). The instruments are programmed for a limited number of uses to ensure reliability and consistent performance.

The instruments attach to a re-usable, sterilizable adaptor on the manipulator arm of the Endoscopic Instrument Control System to provide a barrier between the (sterile) instrument and the (non-sterile) manipulator arm. A mounting surface on the adapter provides a means to secure a sterile drape that covers the arm assembly. This allows instruments to be interchangeable during a procedure,

without compromising the sterile barrier. When attached to the manipulator, the instrument is inserted through a cannula mounted to the manipulator.

All instruments have articulations at the distal end that are controlled by the surgeon. The instrument is the "wrist" of the system and provides four (4) degrees of freedom (wrist pitch, wrist yaw, roll and grip). These instruments share similar architecture, materials, and manufacturing processes. The primary difference between the instruments is the tip end effector also known as the "tool end".

Intended Use

The Surgical Endoscopic Instruments including scissors, scalpels, forceps/pick-ups, needle drivers and electrocautery are intended for endoscopic manipulation of tissue, including: grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing.

Design/Risk Management Team

Project Manager/Operations:	Joe Morrison
R&D Project Manager:	Mathew McGowan
Product Supervisor:	Greg Fiegel
QA/Manufacturing:	Jeff Bua
RA:	AJW Technology Consultants
Research & Development/Consulting:	Horizon Product Development,
*Others as Required	

Required document approval signatures will be: Project Manager / Operations; R&D Project Manager; Product Supervisor; and QA. Operations represents quality system management.

Design review approval signatures will be: Project Manager / Operations; R&D Project Manager; Product Supervisor; QA; Management Sponsor; and independent representative. Operations represents quality system management.

Project Milestones and Responsibilities

Describe Design Activities (Project Milestones) and define responsibilities for their implementation. Clearly identify the required acceptance criteria (deliverables) for the beginning and end of each phase of the project and identify when Design reviews are required.

The EndoWrist shall be designed per Rebotix's SOP 1005 "Design Control".

Design and Development Input Phase Deliverables

Risk Management per SOP 1006
- Initial Risk Management Plan

Engineering
- Initial Product Specifications

Design Input Requirements as listed on Project Trace Matrix Form 1005-004 (Input Section).

Project Manager

Design Review Meeting Agenda

Design Review Meeting Minutes per SOP Form 1005-001 Design Review

Target Completion Date: 05/23/2014

Design and Development Input Phase Review Completed On: 05/27/14

Design and Development Output Phase Deliverables

Risk Management
- Risk Management Plan (Review)
- Design FMEA (Hazard Analysis)

Engineering
- Review Updated to Product Specifications

Design
- Software Development Plan
- Software Requirements Specification
- Software Design Specification
- Update Project Trace Matrix, Form 1005-004.
- DMRI, Form 1005-002

Project Manager
- Design Review Meeting Agenda
- Design Review Meeting Minutes per Form 1005-001 Design Review

Target Completion Date: July 21 2014

Design and Development Output Phase Review Completed On: 07/21/14

Design and Development Output Phase Review II Completed On: 6/09/15

Verification Phase Design Review Deliverables

Risk Management
- Risk Management Plan (Review)
- Design FMEA (Review)

Design
- Project Trace Matrix Form 1005-004 (Review Updates).
- Design Verification Plan
- Design Verification Final Report
- Software V & V

Project Manager
- Design Review Meeting Agenda
- Design Review Meeting Minutes per Form 1005-001 Design Review

Target Completion Date: January 12, 2015

Design Verification Phase Review Completed On:_____

Validation Phase Design Review Deliverables

Risk Management

- Risk Management Plan (Review)
- Design FMEA (Review)

Design

- Project Trace Matrix, Form 1005-004(Review Updates).
- Design Validation Plan
- Design Validation Report

Project Manager

- Design Review Meeting Agenda
- Design Review Meeting Minutes per Form 1005-001 Design Review

Target Completion Date: January 13, 2015

Design Validation Phase Review Completed On:_____

Design Transfer Phase Design Review Deliverables

Risk Management
- PFMEA
- Quality Plan
- Risk Management Report

Design
- Review of Design History File per Form 1005-003 Design Transfer
- QA / RA Release of Design for Sale

Project Manager
- Design Review Meeting Agenda
- Design Review Meeting Minutes per Form 1005-001 Design Review

Target Completion Date: January 14, 2015

Design Transfer Phase Review Completed On:_____

Team Requirements, Responsibilities and P.O.C.

Summary of interfaces, including points of contact, phone numbers, mailing addresses, E-mail addresses and responsibilities.

Management Sponsor	David Mixner Rebotix, LLC President 539 Pasadena Ave. S Saint Petersburg FL 33710 Ph: 727.343.5503 Fax: 727.343.4637 davidmixner@rebotix.net

Project Manager/Operations	Joe Morrison Rebotix, LLC Operations Manager 539 Pasadena Ave. S Saint Petersburg FL 33710 Ph: 727.343.5503 Fax: 727.343.4637 joemorrison@rebotix.net
R&D Project Manager	Mathew McGowan Rebotix, LLC R&D Project Manager 539 Pasadena Ave. S Saint Petersburg FL 33710 Ph: 727.343.5503 Fax: 727.343.4637 mattmcgowan@rebotix.net
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Independent Representative	Chris Gibson Rebotix, LLC Materials Manager 539 Pasadena Ave. S Saint Petersburg FL 33710 Ph: 727.343.5503 Fax: 727.343.4637 chrisgibson@rebotix.net
Electrical Engineer, Consultant	Jay Schuenke Horizon Product Development Principle, Director of Design and Development 2873 55th Street North Saint Petersburg FL 33710 Ph: 727.871.8011 Fax: 866.629.5176 jay@horizon-pd.com

Attachment A: Model List

REF	DESCRIPTION
420001	Potts Scissors
420006	Large Needle Driver
420007	Round Tip Scissors
420036	DeBakey Forceps
420048	Long Tip Forceps
420049	Cadiere Forceps
420093	ProGrasp™ Forceps
420110	PreCise™ Bipolar Forceps
420171	Micro Bipolar Forceps
420172	Maryland Bipolar Forceps
420178	Curved Scissors
420179	Hot Shears™ (Monopolar Curved Scissors)
420181	Resano Forceps
420183	Permanent Cautery Hook
420184	Permanent Cautery Spatula
420189	Double Fenestrated Grasper
420190	Cobra Grasper
420194	Mega™ Needle Driver
420205	Fenestrated Bipolar Forceps
420207	Tenaculum Forceps
420227	PK® Dissecting Forceps
420296	Large SutureCut™ Needle Driver
420309	Mega SutureCut™ Needle Driver
420344	Curved Bipolar Dissector

Form 1001-002; Rev A;

DCN 2014-009; Date 05/21/2014

Rebotix

Title: Document Approval Form

DOCUMENTATION TYPE: Design Plan

TITLE / DOCUMENT NO / REVISION:

Design Development Plan "Endowrist", DPPR1001, Rev C

-Changes: Changed to add reference to Outputs Review II meeting; Remove Casica Engineering from Design team as Pete Casica is no longer active on the project; Change target completion dates for remaining design phases.

PREPARED BY: Joe Morrison

DATE: 01/08/2015

APPROVALS

Department	Name	Signature	Date
Qualtiy Assurance:	Jeff Bua		1/8/15
Operations:	Joe Morrison		01/08/15
Member:	David Mixner		1/8/15
R&D Project Manager:	Mathew McGowan		1/8/15
Product Supervisor:	Greg Fiegel		1/8/15